

### REMARKS

The specification has been amended to correct a typographical error. Claims 1-8 and 14-41 have been cancelled without prejudice. Claim 9 has been amended to more clearly describe Applicants' invention. New claims 42-62 have been added. Support for the amendment and the new claims can be found throughout the specification, for example, at pages 15-17. No new matter has been added.

#### Rejection under 35 U.S.C. § 101

Claims 9-13 were rejected by the Examiner as being directed to non-statutory subject matter. Specifically, the Examiner asserts that an active site "is not a composition of matter, but rather a set of three dimensional coordinates," and therefore represent functional descriptive material, which is non-statutory when claimed as descriptive material per se. See the Office Action at pages 2-3. Applicants respectfully disagree.

Applicants have discovered an active site of an N-terminal domain of TNFR-1 associated death domain protein (N-TRADD), where the active site is characterized by a three dimensional structure including the relative structural coordinates of amino acid residues Y16, F18, and H65 according to FIG. 2. See independent claim 9. The relative structural coordinates are not themselves the active site. Rather, coordinates describe the location of atoms in the active site. At page 10, lines 15-19, the specification states:

An "active site" refers to a **region of a molecule or molecular complex** that, as a result of its shape and charge potential, favorably interacts or associates with another agent (including, without limitation, a protein, polypeptide, peptide, nucleic acid, including DNA or RNA, molecule, compound, antibiotic, or drug) *via* various covalent and/or non-covalent binding forces (emphasis added).

At page 14, lines 11-17 the specification states:

...the present invention is directed to an active site of the N-TRADD molecule **characterized by** the three dimensional structure comprising the relative structural coordinates of amino acid residues Y16, F18, and H65 according to

Figure 2,  $\pm$  a root mean square deviation from the conserved backbone atoms of said amino acids of not more than 1.5 Å, or preferably, not more than 1.0 Å, or more preferably not more than 0.5 Å (emphasis added).

The drawings and specification indicate that an active site is a region of a molecule or molecular complex that is characterized by relative structural coordinates. Claims 9-13 therefore are directed to statutory material. Applicants respectfully request that the rejection under 35 U.S.C. § 101 be reconsidered and withdrawn.

**Rejections under 35 U.S.C. § 112, first paragraph**

**Written description**

Claims 9-13 have been rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. Specifically, the Examiner contends that "[t]he only peptide having C-TRAF2 binding site with residues as claimed is TRADD, its N-terminal part in particular." See the Office Action at page 3.

The term "N-TRADD" is introduced at page 1, line 4 of the specification: "... the N-terminal domain of TNFR-1 associated death domain protein ('N-TRADD')." Applicants have amended independent claim 9 to reflect an active site of an N-terminal domain of TNFR-1 associated death domain protein (N-TRADD), rather than a C-TRAF2 binding protein or peptide. The specification clearly describes N-TRADD and an active site of N-TRADD. See the specification at, for example, page 8, lines 13-27, where residues of an N-TRADD active site are described, and at FIG. 2, which provides relative structural coordinates of atoms of the residues. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for lack of written description.

**Enablement**

Claims 9-13 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserts that "...the specification, while being enabling for C-TRAF2

binding site of N-TRADD, does not reasonably provide enablement neither for other active sites, nor for other proteins or peptides." See the Office Action at page 4 (emphasis added).

Applicants have amended independent claim 9 to reflect an active site of an N-terminal domain of TNFR-1 associated death domain protein (N-TRADD), rather than a C-TRAF2 binding protein or peptide, as discussed above. The specification teaches a person skilled in the art to how make and use such an active site. See the specification at, for example, page 8, lines 13-27, pages 25-40, and FIG. 2. Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph for lack of enablement be reconsidered and withdrawn.

#### **New claims**

New claims 42-62 have been added. The new claims read on the elected invention. Claims 42, 49, and 56 are independent. Claim 42 is directed to a three-dimensional model of an N-terminal domain of TNFR-1 associated death domain protein (N-TRADD). The three-dimensional model includes relative structural coordinates of atoms of an active site of N-TRADD. See the specification at, for example, page 15, lines 1-17.

Claim 49 is directed to a machine readable storage medium including a data storage material. The data storage material is encoded with machine readable data including relative structural coordinates of atoms of an N-terminal domain of TNFR-1 associated death domain protein (N-TRADD). Claim 56 is directed to a computer system including machine readable data including relative structural coordinates of atoms of an N-terminal domain of TNFR-1 associated death domain protein (N-TRADD) and programmed to display a three-dimensional model of N-TRADD according to the coordinates. See the specification at, for example, pages 15-17. In light of the Examiner's comments regarding the rejection under 35 U.S.C. § 101 (see above), Applicants believe that claims 49 and 56 are directed to statutory subject matter. See MPEP 2106 IV.B.1.

Applicants believe the new claims are patentable.

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CONCLUSION

Applicants ask that all claims be allowed. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

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